

WE CLAIM:

1. A composition for inducing a semi-synchronous wave of liver cell proliferation *in vivo* comprising tri-iodothyronine (T3) and keratinocyte growth factor (KGF).

2. The composition of claim 1 having a ratio of between about 8:1 and about 1:1 by weight of T3 to KGF.

3. An *in vivo* method for inducing a semi-synchronous wave of liver cell proliferation in an individual comprising concurrently administering an effective amount of T3 and KGF to an individual.

4. The method of claim 3, the amount of T3 administered ranging from about 400 µg per kg of body weight of the individual and about 40 mg per kg of body weight of the individual.

5. The method of claim 4, the amount of T3 administered being about 4 mg per kg of body weight of the individual.

6. The method of claim 3, the amount of KGF administered ranging from about 100 µg per kg of body weight of the individual and about 10 mg per kg of body weight of the individual.

7. The method of claim 6, the amount of KGF administered being about 1 mg per kg of body weight of the individual.

8. The method of claim 3, the T3 and KGF being administered in a ratio of about 4:1 by weight.

20 9. The method of claim 8, the T3 being administered at a dose of about 4 mg per kg of body weight of the individual and the KGF being administered in a dose of about 1 mg per kg of body weight of the individual.

10. The method of claim 3, the T3 being administered subcutaneously.

11. The method of claim 3, the KGF being administered subcutaneously.

12. A method of treatment comprising

concurrently administering an effective amount of T3 and KGF to an individual an effective amount of time prior to the administration to the individual of a liver-directed gene transfer vector.

5

13. The method of claim 12, further comprising administering to the individual a liver-directed gene transfer vector.

14. The method of claim 13, the liver-directed gene transfer vector comprising a nucleic acid encoding a therapeutically active RNA, polypeptide or protein.

15. The method of claim 13, the liver-directed gene transfer vector comprising a retroviral vector.

16. The method of claim 15, the liver directed gene transfer vector further comprising a cationic liposome.

17. The method of claim 16, the cationic liposome being DiOctadecylamidoGlycylSpermine (DOGS).

18. The method of claim 13, the liver-directed gene transfer vector transducing on average at least between about 1 in 7.5 liver cells induced to proliferate and about 1 in 5 liver cells induced to proliferate.

19. The method of claim 13, the liver-directed gene transfer vector being administered 20 between about hour 6 and about day 14.

20. The method of claim 19, the liver directed gene transfer vector being administered between about hour 24 and about day 8.

21. The method of claim 13, the liver directed gene transfer vector transducing liver cells selected from the group consisting of biliary tract cells and hepatocytes.

22. The method of claim 21, the liver directed gene transfer vector transducing hepatocytes selected from the group consisting of periportal hepatocytes and mid-zonal hepatocytes.

5 23. An organ comprising liver cells transduced by the method of claim 13.

24. The organ of claim 23, the liver cells comprising at least one cell from the type selected from group consisting of hepatocytes and biliary duct cells.

25. An animal having a liver genetically modified by the method of claim 13.

RECEIVED  
U.S. PATENT AND TRADEMARK OFFICE